

IN THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claims 1-7 (canceled).

Claim 8 (new): 8-hydroxy-5-[(1R)-1-hydroxy-2-[[(1R)-2-(4-methoxyphenyl)-1-methyl ethyl]amino]ethyl]-2(1H)-quinolinone monohydrochloride having a melting range of 180-200°C determined by differential scanning calorimetry and a X-ray powder diffraction pattern having one or more of the following characteristic peaks: 12.2; 13.6; 16.3; 18.0; 18.2; 19.2; 21.4; 21.9; 22.8; 23.5; 24.2; 24.9; 26.6; 28.5; 29.4; 29.9; and 33.9 ± 0.2 degrees/ 2θ and a degree of crystallinity, expressed as weight % based on the total weight of said 8-hydroxy-5-[(1R)-1-hydroxy-2-[[(1R)-2-(4-methoxyphenyl)-1-methyl ethyl]amino]ethyl]-2(1H)-quinolinone monohydrochloride, of at least 90 weight %.

Claim 9 (new): 8-hydroxy-5-[(1R)-1-hydroxy-2-[[(1R)-2-(4-methoxyphenyl)-1-methyl ethyl]amino]ethyl]-2(1H)-quinolinone monohydrochloride according to Claim 8 having a melting range of 185-195°C determined by differential scanning calorimetry.

Claim 10 (new): 8-hydroxy-5-[(1R)-1-hydroxy-2-[[(1R)-2-(4-methoxyphenyl)-1-methyl ethyl]amino]ethyl]-2(1H)-quinolinone monohydrochloride according to Claim 8 having a degree of crystallinity, expressed as weight % based on the total weight of said 8-hydroxy-5-[(1R)-1-hydroxy-2-[[(1R)-2-(4-methoxyphenyl)-1-methyl ethyl]amino]ethyl]-2(1H)-quinolinone monohydrochloride, of at least 93 weight %.

Claim 11 (new): 8-hydroxy-5-[(1R)-1-hydroxy-2-[(1R)-2-(4-methoxyphenyl)-1-methyl ethyl]amino]ethyl]-2(1H)-quinolinone monohydrochloride according to Claim 8 having a degree of crystallinity, expressed as weight % based on the total weight of said 8-hydroxy-5-[(1R)-1-hydroxy-2-[(1R)-2-(4-methoxyphenyl)-1-methyl ethyl]amino]ethyl]-2(1H)-quinolinone monohydrochloride, of at least 95 weight %.

Claim 12 (new): A process for preparing 8-hydroxy-5-[(1R)-1-hydroxy-2-[(1R)-2-(4-methoxyphenyl)-1-methyl ethyl]amino]ethyl]-2(1H)-quinolinone monohydrochloride according to Claim 8, said process comprising:

crystallizing or re-crystallising 8-hydroxy-5-[(1R)-1-hydroxy-2-[(1R)-2-(4-methoxyphenyl)-1-methyl ethyl]amino]ethyl]-2(1H)-quinolinone monohydrochloride from an aqueous ethanol solution and diisopropyl ether,

wherein said aqueous ethanol solution is concentrated to a volume comprised between 1/2 and 1/3 of the initial volume and diisopropyl ether is added to the concentrated solution in at least 5 minutes, to obtain crystallized 8-hydroxy-5-[(1R)-1-hydroxy-2-[(1R)-2-(4-methoxyphenyl)-1-methyl ethyl]amino]ethyl]-2(1H)-quinolinone monohydrochloride.

Claim 13 (new): A process according to Claim 12, further comprising:

re-crystallization said crystallized 8-hydroxy-5-[(1R)-1-hydroxy-2-[(1R)-2-(4-methoxyphenyl)-1-methyl ethyl]amino]ethyl]-2(1H)-quinolinone monohydrochloride from a protic solvent comprising ethanol, isopropanol or an aqueous mixture thereof.